

REMARKS

Status of the Claims

Applicants wish to thank Examiner Kubelik for extending the courtesy of the telephonic interview held on July 13, 2004 with Applicants' representative Carol Fang. During this interview, a number of issues were clarified which have helped Applicants to more fully address the concerns of the Examiner. In particular, new claims 66-86 were discussed. Based on the Examiner's comments during the interview, it is Applicants' understanding that in view of the amendments to the claims, the Examiner is favorably disposed toward withdrawing the rejections under 35 U.S.C. § 112, first paragraph. Applicants thank Examiner Kubelik for her time.

After entry of this amendment, claims 1-65 have been cancelled and claims 66-86 are pending. Claims 66-86 correspond to cancelled claims 16-23, 31 and 53-64. Therefore, new claims 66-86 add no new matter.

Claims 16-23, 31 and 53-65 are rejected under 35 U.S.C §112, first paragraph as allegedly lacking adequate written description and enablement. Claims 16-23, 31 and 53-65 are rejected under 35 U.S.C §112, second paragraph, as allegedly indefinite. These objections are addressed below in the order presented by the Examiner.

As an initial matter, Applicants note that several of the references cited in the response to the Office Action mailed August 21, 2003 were inadvertently omitted from the correspondence to the USPTO. Applicants hereby submit these references for the consideration of the Examiner.

Rejections under 35 USC §112, first paragraph

1. Written Description

The Examiner initially rejected claims 16-23, 31 and 53-65 under 35 U.S.C §112, first paragraph, as allegedly lacking adequate written description.

The written description requirement is satisfied when the specification describes the claimed invention in sufficient detail that one of skill in the art can reasonably conclude that the inventor had possession of the claimed invention (*see, e.g.*, MPEP § 2163(I), citing *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 19 USPQ2d 1111 (Fed. Cir. 1991)). Possession can be shown by describing sufficient distinguishing characteristics (*see, e.g.*, MPEP § 2163(I), citing *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 48 USPQ2d 1641 (1998); *University of California v. Eli Lilly*, 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997); and *Amgen Inc. v. Chugai Pharmaceutical*, 927 F.2d 1200, USPQ2d 1016 (Fed. Cir. 1991)). In particular, the written description requirement for a claimed genus may be satisfied by description of a representative number of species (*see, e.g.*, MPEP § 2163(II)(3)(a)(ii)). Description of a representative number of species does not require the description to be of such specificity that it would provide individual support for each species that the genus represents (*see, id.*). Description of a single species may be sufficient to support a genus (*see, id.*)

As discussed during the interview, the presently pending claims 66-86 are fully described in the specification in such a way as to reasonably convey to one of skill in the art that the inventors had possession of the claimed invention. The amended claims are directed to nucleic acid molecules comprising a nucleic acid sequence that encodes a vacuole targeting polypeptide operably linked to a nucleic acid sequence that encodes a biotin binding protein selected from avidin, streptavidin, CORE streptavidin, synthetic CORE streptavidin, and SYNSAV.

As discussed during the interview, Applicants respectfully assert that the specification provides ample written description to convey to one of skill in the art that the Applicants were in possession of the presently claimed nucleic acid molecules at the time of filing. First, the specification at page 11, line 27 to page 12, line 1, explicitly sets forth many representative species of vacuole targeting sequences known in the art including, for example, polypeptides targeting barley lectin, sweet potato sporamin, tobacco chitinase, bean phytohemagglutinin, and potato proteinase inhibitors. In addition, the specification at page 13, line 32 to page 14, line 19 describes biotin binding proteins, including, *e.g.*, avidin, streptavidin, CORE streptavidin, synthetic CORE streptavidin, and SYNSAV. Thus, there is ample disclosure

in the specification to convey to one of skill in the art demonstrate that the inventors were in possession of the claimed genus of nucleic acid molecules at the time of filing.

In view of the foregoing remarks, Applicants assert that written description has been satisfied for the claims by the teachings of the specification as originally filed and respectfully request withdrawal of this aspect of the rejection under 35 U.S.C. § 112, first paragraph.

2. Enablement

Claims 16-23, 31 and 53-65 were initially rejected under 35 U.S.C. §112, first paragraph, as allegedly lacking enablement. In making the rejection, the Examiner acknowledges that the specification enabled claims to nucleic acids that encode a chimeric protein comprising *any* vacuole targeting sequences operably linked to avidin or streptavidin, cells and plants transformed with those nucleic acids, and methods for using the cells in plants to produce the protein, but alleged that the specification did not enable claims to functional equivalents of biotin binding proteins.

As set forth in MPEP §2164.01, a particular claim is enabled by the disclosure in an application if the disclosure, at the time of filing, contains sufficient information so as to enable one of skill in the art to make and use the claimed invention without undue experimentation. The fact that experimentation may be complex does not necessarily make it undue, if the art typically engages in such experimentation (*see, id.*).

As discussed during the interview, the amended claims are directed to nucleic acid molecules comprising a nucleic acid sequence that encodes a vacuole targeting polypeptide operably linked to nucleic acid sequence that encodes a biotin binding protein selected from the avidin, streptavidin, CORE streptavidin, synthetic CORE streptavidin, and SYN SAV. During the interview, the Examiner indicated that the amended claims were enabled by the instant specification. Moreover, Applicants respectfully submit that the specification explicitly describes several biotin-binding sequences suitable for use in the presently claimed invention, including avidin, streptavidin, CORE streptavidin, and synthetic CORE streptavidin (*see, e.g.,*

page 13, line 32 to page 14, line 19). Finally, the specification provides multiple working examples which unequivocally demonstrate that nucleic acid molecules comprising a nucleic acid sequence encoding a vacuole targeting polypeptide operably linked to a nucleic acid sequence encoding avidin or streptavidin sequences can be constructed and expressed, and that the expressed polypeptides are effective in pest control (*see, e.g.*, Examples 2-9 at page 27, line 1 to page 46, line 21). Therefore, based on the guidance in the specification one of skill in the art would be able to practice the full scope of the presently claimed invention without undue experimentation.

Accordingly, Applicants respectfully request withdrawal of this aspect of the rejection under 35 U.S.C. § 112, first paragraph.

Rejections under 35 USC §112, second paragraph

Claims 16-23, 31 and 53-65 were initially rejected under 35 U.S.C. §112, second paragraph as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which the Applicants regard as the invention.

As set forth in MPEP §2173.02 “definiteness of claim language must be analysed in the light of (A) content of the application; (B) the teachings of the prior art; and (C) the claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made”.

1. Claim 16

Claim 16 was rejected as allegedly indefinite for the recitation “functionally equivalent variant thereof.” As discussed with the Examiner on July 13, 2004, the presently pending claims lack this recitation. Accordingly, Applicants respectfully request withdrawal of this rejection.

2. Claims 21 and 31

Claims 21 and 31 have been rejected as allegedly indefinite for the recitation "the polypeptide encoded by the nucleic acid according to claim 16". Claims 21 and 31 have been cancelled. Accordingly, Applicants respectfully request withdrawal of this rejection.

3. Claim 65

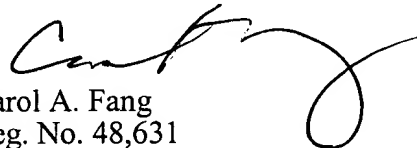
Claim 65 has been rejected as allegedly indefinite for the "nucleic acid sequence of claim 1." Claim 65 has been cancelled. Accordingly, Applicants respectfully request withdrawal of this rejection.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance and an action to that end is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, the Examiner is invited to telephone the undersigned at 415-576-0200.

Respectfully submitted,


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